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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,161	11/20/1998	YOKE MIN SIN	1459-005B	8822

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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/196,161

Applicant(s)

SIN ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of species SEQ ID NO: 1, claims 1-8 and 24, in the reply filed on May 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 25-35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 20, 2004.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. It is noted that the prior art rejection of claims 1, 3, 4 and 6-8 rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al (Dev. Biol. Stand. 1997, 90:461 Library of Congress stamped date is August 21, 1997) is withdrawn in view of the amendment to the claims filed September 4, 2003.
5. It is noted that the prior art rejection of claims 2 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (1997) as applied to claims 1, 3, 4 and 6-8 above, and further in view of Clark et al (PNAS, 1992, 89:6363-6367) and Smith et al (Gene, 1998, 67:31-40) is withdrawn in view of the amendment to the claims filed September 4, 2003.

6. Claims 1-8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al 1992 (PNAS USA, July, 1992, 89:6363-6367) or He et al 1997 (Aquaculture, 1997, 158:1-10).

The claims are directed to a vaccine for immunizing fish against ciliated ectoparasitic protozoans comprising an effective amount of a recombinant fusion protein (GST-iAgI) derived from an artificial DNA sequence for immobilization antigen, repeat I of *Ichthyophthiirus multifiliis* wherein said sequence is SEQ ID NO: 1 and a medium comprising at least one of buffers, adjuvants, immuno-stimulants or carriers. The vaccine, when injected into a fish, provides effective protection against white spot disease caused *Ichthyophthiirus multifiliis*. The fusion protein is produced using *E. coli*.

Clark et al discloses the expression of the immobilization antigen (i.e. iAgI); the cDNA encode a protein of 394 amino acids with a tandemly repeated structure characteristic of the i-antigen of other ciliated parasites (abstract). Clark et al discloses that the immobilization antigens of *I. multifiliis* are analogous to free-living ciliates and parasitic protozoa; and "...that transcript levels increase in parallel with the infectivity of the organism bears on the functional role in this system and is consistent with previous observations suggesting that the i-antigens of *Ich* are involved in the development of protective immunity in fish. (p. 6363, col. 2; see also p. 6367, col. 2). The materials and methods disclose how to obtain a recombinant immobilization antigen (p. 6363-6365). Clark et al discloses the entire amino acid sequence as set forth in SEQ ID NO: 1 (see figure 1). Clark et al discloses "on a more applied level, because the i-antigens of *Ich* interact with the immune system of fish, they have potential as protective immunogens and may

be of practical use in the treatment of a pathogen with major impact on aquaculture worldwide.” (p. 6367, col. 2).

It is noted that the prior art does not specifically recite a medium (buffer, adjuvant, immunostimulant, or carrier). However, it would be inherent that a vaccine composition would comprise a buffer, adjuvant or carrier of some kind, since the art discloses the use of the antigen in a vaccine for protection against disease.

Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine with the vaccine of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed vaccine and the vaccine of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

7. Claims 1-8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al 1997 (Aquaculture, 1997, 158:1-10).

He et al discloses a potential antigenic epitope of the 48 kDa immobilization antigen of the *I. multifiliis* (i-AgI) that was cloned into a bacterial expression vector and the gene construct was introduced into *E. coli* and the glutathione S-transferase-iAgI (GST-iAgI) fusion protein was successfully expressed (abstract; materials and methods). He et al discloses that antisera against GST-iAgI fusion protein from catfish showed a positive reaction with a tomite protein of about 48 kDa, suggesting that the recombinant protein contains an antigenic epitope of i-AgI (abstract). He et al discloses that the recombinant GST-iAgI fusion protein can be used as a potential vaccine against the infection of *I. multifiliis* (abstract). He et al

discloses that *I. multifiliis* is a ciliated protozoan parasite and known to cause white spot disease (pp. 1-2). The cDNA encode a protein of 394 amino acids with a tandemly repeated structure characteristic of the i-antigen of other ciliated parasites (abstract). He et al discloses the same amino acid sequence of the iAgI as set forth in the claimed SEQ ID NO: 1 (see figure 1A). He et al discloses the antigen in buffer as well as mixed with adjuvant (see pp. 4-5). He et al discloses, "the immunogenicity of the GST-iAgI fusion protein was determined in goldfish immunized with the fusion protein. The results showed that the immunized fish had a significantly higher survival rate than that of the control fish after they were challenged with the infectious tomites of *I. multifiliis*. All these results indicated that the synthetic vaccine does share a similar antigenic determinant with a tomite's protein of *I. multifiliis*." (p. 8).

Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine with the vaccine of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed vaccine and the vaccine of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

8. Claims 1-8 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "an artificial DNA sequence". SEQ ID NO: 1 is an amino acid sequence only. The claim language should be consistent with the

sequence that is claimed. Further, does applicant intend the entire sequence of SEQ ID NO: 1 or a portion of it as indicated by the claim language?

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record in this application.

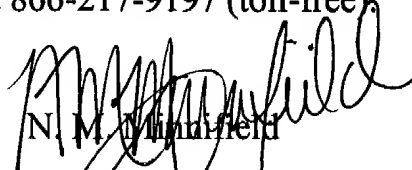
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

August 30, 2004